[Submitting Counsel on Signature Page]

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE JUUL LABS, INC., MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	Case No. 19-md-02913-WHO
This Document Relates to: ALL ACTIONS	**PLAINTIFFS' OPPOSITION TO DEFENDANT JUUL LABS INC'S MOTION TO DISMISS CLAIMS PREEMPTED BY FEDERAL LAW (MOTION #2)**
	Judge: **Hon. William H. Orrick** **Date:** **September 21, 2020** **Time:** **9:00 a.m.** **Ctrm.:** **2**

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I. INTRODUCTION

There is no doubt that, when granting the FDA authority over tobacco products, Congress was well aware of the potential for the co-existence of private litigation under state law. How could it not be? The decades-long fraud perpetrated by the cigarette industry on the American people was exposed not in Congressional hearing rooms or the Federal Register, but in courtrooms; and the truth was revealed not through federal intervention, but via the tireless efforts of state and private plaintiffs. *See* Michael V. Ciresi et al, *Decades of Deceit: Document Discovery in the Minnesota Tobacco Litigation*, 25 Wm. Mitchell L. Rev. 477 (1999); Christopher N. Banthin & Richard A. Daynard, *Room for Two in Tobacco Control: Limits on the Preemptive Scope of the Proposed Legislation Granting FDA Oversight of Tobacco*, 11 J. Health Care L. & Pol'y 57, 70 (2008) ("In addition to the traditional role of providing at least the possibility of compensating the millions of potential victims of the industry, tobacco litigation has under-girded much of tobacco control strategy primarily by creating opportunities for intervention.").

Cognizant of that history, Congress chose not to remain silent and leave it to the courts to identify and police the limits of traditional state authority in the areas newly subject to federal regulation. Instead, Congress wrote what may be the most detailed and carefully-crafted preemption provision in the U.S. Code, with a thumb firmly on the scale against preemption. It is no accident that the provision at issue in this case is titled "Preservation of State and Local Authority." 21 U.S.C. § 387p. As written, the Tobacco Control Act (TCA)[1] delineates between preempted and permitted state law with surgical precision: a narrow preemption provision affecting only state requirements "different from, or in addition to" regulations relating to product standards, labeling, manufacturing, and the like; a preservation clause and an exception clause, both protecting vast swaths of state authority concerning the sale, advertising, and use of tobacco products; and a "rule of construction" establishing categorical exclusion from preemption of all product liability claims. *Id.*

In light of the plain text of the TCA, JLI's brief is nothing short of astonishing. According

[1] Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, 123 Stat. 1776 (2009).

to JLI, Congress simply got it wrong—it turns out that the TCA preempts *all* state-law claims having anything to do with tobacco products deemed subject to FDA authority. This sweeping assertion, akin to field preemption, would give the cigarette industry the broad immunity from damages actions it has sought for decades but never achieved. That would be wonderful for JLI (not to mention R.J. Reynolds and Philip Morris), but has nothing to do with the statute Congress actually wrote and which this Court is duty-bound to apply.

The "purpose of Congress is the ultimate touchstone in every pre-emption case," *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008) (citation omitted), and it is the "plain wording of the [preemption] clause[] which necessarily contains the best evidence of Congress' pre-emptive intent." *In re Volkswagen "Clean Diesel" Mktg., Sales Prac. & Prod. Liab. Litig.*, 959 F.3d 1201, 1211 (9th Cir. 2020) (citation omitted). Yet JLI's brief contradicts the "plain wording" at every turn. In the TCA, Congress says that claims "relating to ... advertising and promotion" are not preempted, 21 U.S.C. § 387p(a)(2)(B); per JLI, "deceptive advertising claims" are preempted, ECF 627 at 9. Congress says that the FDA's authority does not "affect any action or the liability of any person under the product liability law of any State," 21 U.S.C. § 387p(b); once again, per JLI, Congress is wrong: "any purported product-liability claims" are impliedly preempted, ECF 627 at 17. Where the TCA does displace state law, it does so only in connection with specific federal "requirements." 21 U.S.C. § 387p(a)(2)(A). The FDA has not issued any "requirements" related to JLI's product design; no matter, according to JLI: "design-based claims are expressly preempted," ECF 627 at 6. And so on.

Preemption is a creature of statute, and is disfavored where, as here, state action is squarely within "the historic primacy of state regulation of matters and health and safety," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), and there is a "long history of tort litigation," *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 439 (2005). JLI's motion asks this Court to endorse a vague and boundless preemption analysis, untethered to and in contravention of the statutory text, uncritically trammeling of traditional state interests, and leaving injured persons, schools, and municipalities without a remedy. JLI's motion should denied.

II. STATUTORY AND REGULATORY BACKDROP

In enacting the TCA, Congress sought to stem the tide of tobacco-related illness and death. TCA, 123 Stat. at 1777 (recognizing that "[t]obacco use is the foremost preventable cause of premature death in America" and that reducing youth tobacco use could save millions of lives). The TCA prohibited tobacco companies from selling new tobacco products unless the manufacturer could prove to the FDA that the products were either "substantially equivalent" to those already available, or that permitting their sale would be "appropriate for the protection of the public health." 21 U.S.C. § 387j. In addition to the obligation to implement these "premarket" review requirements, the TCA gave the FDA power to regulate tobacco products' sales, labeling, and advertising. 21 U.S.C. § 387c.

In 2016, the FDA issued a rule deeming various products, including e-cigarettes, covered "tobacco products." Deeming Rule, 81 Fed. Reg. 28,973-01 (May 10, 2016). JLI's motion is long on what the FDA *might* do or *could* have done, but short on what the Deeming Rule actually *did*: not that much. The Rule subjected e-cigarettes automatically to certain standard obligations applicable under the statute to all covered products (such as potential FDA action against adulterated or misbranded products, registration, information submission, and a prohibition on free samples). *Id.* at 28,976. Beyond that, the Deeming Rule did little, establishing only "three restrictions for covered tobacco products: (1) Requirement for a minimum age of purchase; (2) requirement for health warnings for product packages and advertisements ...; and (3) prohibition of vending machine sales." *Id*. Specifically, the FDA set out a single "Minimum Required Warning Statement[]" to be included on JLI's label: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." 21 C.F.R. § 1143.4(a)(1).

The FDA did not conduct the premarket review required by the TCA nor did it consider or approve any manufacturer's product design, manufacturing, or marketing. Instead, in what it termed an "exercise of enforcement discretion," the agency stated that "newly deemed, new tobacco products" would not "be subject to enforcement" during "compliance periods" that the Deeming Rule established. *Id.* at 28,978. And the FDA has since reiterated that enforcement discretion "does not in any way alter the fact that it is illegal to market any new tobacco product

without premarket authorization." April 2020 Guidance at 3.[2] Nothing about the Deeming Rule gave JLI's products or practices the imprimatur of federal approval. *See Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 492 (D. Md. 2019) (finding the Deeming Rule an unlawful "across-the-board suspension of the Tobacco Control Act's premarket approval process").

III. ARGUMENT

A. The Court presumes against preemption of state regulation.

Preemption analysis is guided by the presumption that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 757 (9th Cir. 2015) (quoting *Rice v. Santa Fe Elev. Corp.*, 332 U.S. 218, 230 (1947)). JLI contends that no "presumption against preemption" applies where there is an express preemption clause, but the Supreme Court disagrees: if the preemption clause "is susceptible of more than one plausible reading," the Court "accept[s] the reading that disfavors pre-emption." *Altria Grp.*, 555 U.S. at 77. The presumption applies not only "to the question whether Congress intended any pre-emption at all," but also "to questions concerning the *scope* of its intended invalidation of state law." *Lohr*, 518 U.S. 485. This litigation also involves an industry with a "long history of tort litigation against manufacturers," lending further force to the presumption, "for Congress surely would have expressed its intention more clearly if it had meant to deprive injured parties of a long available form of compensation." *Bates*, 544 U.S. at 432-33.

JLI relies on *Atay v. City of Maui*, but there the court noted only that the best method of discerning "Congress' pre-emptive intent" is to begin "with the plain wording of the statute" and when the statute "speaks expressly to the questions at issue," there is no need for any presumption. 842 F.3d 688, 699 (9th Cir. 2016). This notion does not conflict with the general rule that where preemptive intent is not clear from the express language, a presumption against preemption exists. JLI wants to have it both ways, asking this Court to disregard the plain text of the express preemption provision and undertake a limitless implied preemption analysis, while at

[2] Exhibit 3 to the Gildersleeve Declaration, ECF 631-3.

the same time relying on that provision's existence to preclude the ordinary presumption against preemption. That makes no sense. Here, the plain wording of the express preemption provision dispels JLI's preemption claims, no presumption necessary. But, to the extent the Court sees any ambiguity, that ambiguity should be construed against preemption just as it would be in the implied preemption context. *See, e.g.*, *Bates*, 544 U.S. at 449. And, of course, the presumption is fully applicable to JLI's against implied preemption arguments. *See Atay*, 842 F.3d at 699.

B. The TCA expressly preserves Plaintiffs' claims.

Disposition of JLI's motion begins and ends with the text of the preservation and preemption section of the TCA, 21 U.S.C. § 387p, the full text of which appears in the Appendix.

1. The TCA expressly preserves product liability claims.

The TCA delineates between preserved and preempted state law claims with surgical precision. One category of claims that Congress expressly preserved are product liability claims. In the "rule of construction," Congress explicitly stated that "[n]o provision of this chapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 387p(b). The referenced "chapter" in the statute is Chapter 9 of Title 21 of the U.S. Code—the Federal Food, Drug, and Cosmetic Act (FDCA), which the TCA amended. This Court had no occasion to consider the rule of construction in *Colgate v. JUUL Labs., Inc.*, for the preemption analysis there focused only on "false advertising claim[s]," and the case did not allege personal injury. 345 F. Supp. 3d 1178, 1187 (N.D. Cal. 2018). Consequently, the parties ignored the rule of construction, devoting 2 footnotes and 1 sentence to it in briefing.

Reading the text, the language is striking—an unequivocal command that no aspect of the FDA's new authority would have any effect on any product liability claims. *See* Banthin & Daynard, 11 J. Health Care L. & Poly at 74 (rule of construction "would clearly preclude the potential for legal preemption of tobacco litigation"). This makes perfect sense: when the TCA was enacted, as today, many tort lawsuits against cigarette companies were pending, leaving no doubt that many would be filed in the future. It would have been shocking for a Congress well aware of the "400,000 deaths in the United States each year" and "8,600,000 chronic illnesses"

caused by tobacco, 123 Stat. at 1777, to permit federal regulation to snuff those lawsuits out and leave victims with no relief. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

The plain text of the statute reflects its history. Congress drew on the FDA's 1996 attempt to regulate the tobacco industry, an action found to exceed the agency's then-existing authority in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). The TCA resurrected the 1996 rule, requiring the FDA to "publish ... a final rule ... identical in its provisions to" the 1996 tobacco rule, but updated to conform with the particulars of the TCA. 21 U.S.C. § 387a-1(a)(2). Why does that matter? Because the FDA in 1996 considered whether federal tobacco regulation would preempt "product liability claims," 1996 Tobacco Rule, 61 Fed. Reg. 44,396, 44,550 (Aug 28, 1996),[3] and concluded it would not: "FDA is aware of no tort claims against tobacco products that will be preempted." *Id.* There is a direct line from the FDA's position in 1996 to the express Congressional text in 2009, a line reflecting real-world facts—a "long history of tort litigation"—that the Supreme Court says weighs against preemption. *Bates*, 544 U.S. at 432. In other words, every available interpretive tool—text, history, and precedent—points in the same direction: no product liability claim against JLI is preempted. *See Haglund v. Philip Morris, Inc.*, No. 12367, 2009 WL 3839004, at *13 (Mass. Super. Oct. 20, 2009) ("[T]he Act ... expressly does not preempt state law products liability actions concerning tobacco products.").

How does JLI respond to the unrelenting pull of text, history, and precedent? Easy. By ignoring it under the guise that a "saving clause … does not foreclose the application of ordinary implied preemption principles." ECF 627 at 17. While true in the abstract, that principle has no application where, as here, the rule of construction (the "saving clause") unambiguously protects product-liability claims. JLI relies on *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 868 (2000), where the Supreme Court held that state tort actions conflicting with NTHSA airbag regulations could be preempted despite a "saving clause" providing that "'[c]ompliance with' a

[3] Full title: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.

federal safety standard 'does not exempt any person from any liability under common law.'" *Id.* at 868 (quoting 15 U.S.C. § 1397(k) (1988)). The Court interpreted this unusual language narrowly: to "simply bar a special kind of defense, namely, a defense that compliance with a federal standard automatically exempts a defendant from state law." *Id.* at 869. Had Congress intended the saving clause in *Geier* to limit "a federal claim of preemption" rather than merely provide a "state-law compliance defense," it would not "have insisted on a compliance-with-federal-regulation precondition to the provision's applicability." *Id.* at 870. As the Ninth Circuit just recently explained, "this unremarkable principle" articulated in *Geier* "means only that a court must interpret a saving clause as it would any statutory language: giving effect to its plain language and meaning in a way that best comports with the statute as a whole." *Volkswagen*, 959 F.3d at 1214.[4] Here, JLI offers no argument, because there is none, that the rule of construction means anything other than what it says: product liability claims are not preempted.[5]

That leaves the question of which claims arise "under the product liability law of any State." 21 U.S.C. § 387p(b). JLI correctly points out that the phrase elsewhere in the FDCA has been understood to incorporate each state's definition of "product liability." *See, e.g., In re Tylenol (Acetaminophen) Mktg., Sales Prac. & Prods. Liab. Litig.*, No. 13-2436, 2015 WL 7076012, at *6 (E.D. Pa. Nov. 13, 2015) (21 U.S.C. §379r(e), applicable to OTC drugs); *Faustino v. Alcon Labs., Inc.*, No. 15-4145, 2015 WL 12839161, at *3 (C.D. Cal. Sept. 22, 2015), *aff'd*, 692 F. App'x 819 (9th Cir. 2017) (21 U.S.C. § 379s(d), applicable to cosmetics). As a general matter, it is unlikely that the claims asserted in the CAC or the PEC qualify as product-liability claims under the laws of most states, which typically require assertions of personal injury to

[4] JLI also cites *Nat'l Fed. of the Blind v. United Airlines Inc.*, 813 F.3d 718 (9th Cir. 2016). But *Nat'l Fed.* is the same as *Geier*. The saving clause there "preserve[d] only "other *remedies* provided by law," and so was inapplicable on its terms to the "state statutes prescribing substantive standards of care" at issue. *Id.* at 731 (quoting 49 U.S.C. § 40120(c)).

[5] JLI cites cases about other rules of construction in the FDCA, but those provisions have different language than the TCA, exempting product liability claims from "this *section*" (the express preemption provision) rather than "this *chapter*" as in the TCA (meaning all of the FDA's new tobacco authority). The cases JLI cites make this point explicitly. *See Greager v. McNeil-PPC, Inc.*, 414 F. Supp. 3d 1137, 1141-42 (N.D. Ill. 2019) (emphasizing the words "in this section" in italics and bold); *Batoh v. McNeil-PPC, Inc.*, 167 F. Supp. 3d 296, 31 n.19 (D. Conn. 2016) ("that provision only limits the scope of the express preemption clause in § 379r(a)"). And of course, Congress's choice to use different language in the TCA must be honored.

support a product liability claim. *See Tylenol*, 2015 WL 7076012, at *6 n.20.

But most or all of the claims asserted in the PIC likely do so qualify. For example, JLI asserts that claims sounding in warranty and unjust enrichment categorically are not product-liability claims, but the *Tylenol* court found that Alabama law included "misrepresentation in the marketing of a product" encompassed within the meaning of "product liability action." 2015 WL 7076012, at *6. And JLI's citations to cases where "damage[s] consists solely of economic losses," ECF 627 at 18, are off-point because the PIC asserts personal injury. Regardless, to the extent that the Court's preemption determination turns on application of the product-liability saving clause, the prudent approach is to apply that ruling in the context of bellwethers.[6]

2. Product design claims are not preempted because the FDA has not imposed any product design "requirements."

Subject to the exception clause, the TCA provides that "No State ... may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards...." 21 U.S.C. § 387p(a)(2). The FDA, by declining to conduct premarket review, has not imposed any "requirement[s] ... relating to tobacco product standards" and so no design-related claims are encompassed by the preemption clause.

Nonetheless, JLI contends that "[t]he FDA has exercised its authority over the design of JUUL products." ECF 627 at 6. But a federal court has found precisely the opposite: that the FDA has "abdicat[ed] its statutory duty to review new tobacco products" by "allowing unapproved tobacco products to be manufactured, advertised, and sold." *Am. Acad.*, 379 F. Supp. 3d at 492; *see also Nicopure Labs., LLC v. FDA*, 266 F. Supp. 3d 360, 376 (D.D.C. 2017), *aff'd*, 944 F.3d 267 (D.C. Cir. 2019) (more charitably: "the agency opted to implement the statutory requirement more gradually"). And the FDA itself has been clear that no such "authorization" has occurred: "all tobacco products ... must meet all the requirements for a premarket authorization ... before the FDA can issue such an authorization," Deeming Rule, 81 Fed. Reg. at 28, 998; and "all deemed

[6] JLI says that Plaintiffs have a "burden," but preemption is an affirmative defense for which JLI bears the burden of persuasion. *Dilts v. Penske Log., LLC*, 769 F.3d 637, 649 (9th Cir. 2014).

new tobacco products on the market without authorization are illegally marketed products," April 2020 Guidance at 10. *See also* Deeming Rule, 81 Fed. Reg. at 29,003 (rejecting calls to delay the Rule until the FDA issued product and manufacturing standards, and explaining that the agency needed more product-specific information before promulgating such standards).

JLI's reliance on FDA "authority" is misplaced. The preemption clause speaks of federal "requirements," not federal "authority," and there are no such requirements related to design. *See Freightliner Corp. v. Myrick*, 514 U.S. 280, 286 (1995) ("[T]he absence of regulation [does not] itself constitute[] regulation."); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002) ("quite wrong to view" a decision "not to adopt a regulation ... as the functional equivalent of a regulation"). For example, in *GoodCat, LLC v. Cook*, an e-liquid manufacturer asserted certain Indiana restrictions were "different from, or in addition to," federal requirements relating to adulteration, premarket review, and good manufacturing standards. 202 F. Supp. 3d 896, 910 (S.D. Ind. 2016). The court rejected the preemption challenge, explaining that "the preemption clause in Section 387p triggers only when a state or local measure "is different from, or in addition, any federal *requirement*," and "the FDA has not issued products standards or good manufacturing practice regulations." *Id.* at 913 (citation omitted, emphasis in original).

3. <u>Plaintiffs' labeling and mislabeling claims are not preempted.</u>

Subject to the exception clause and rule of construction, the TCA preempts state law "different from, or in addition to," any federal "requirement ... relating to ... labeling," 21 U.S.C. § 387p(a)(2)(A). Upon deeming JLI's products "covered tobacco products," the FDA set out a "Minimum Required Warning Statement[]" to be included on the label: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." 21 C.F.R. § 1143.4(a)(1).

In *Colgate*, this Court analyzed both the statute and the regulation and reached two holdings. *First*, the Court held that the FDA warning preempted labeling claims that "JUUL should have warned consumers that the pharmacokinetics of JUUL's nicotine formulation contained in JUUL's pods ... deliver[ed] an exceptionally potent dose of nicotine compared to traditional cigarettes." 345 F. Supp. 3d at 1188; *see also id.* at 1189 ("To the extent that plaintiffs' claims are based on the product label failing to disclose the greater potency and addictiveness of

JUUL's benzoic acid and nicotine salt formulation, JUUL's motion to dismiss is granted."). Plaintiffs do not challenge that holding, which was applicable to the false advertising claims in *Colgate*.[7] Neither the CAC nor the PEC advances claims based on the omission or inadequacy of nicotine-addiction warnings on the label. And the failure to warn claims in the PIC are product liability claims exempted from preemption by the rule of construction not at issue in *Colgate*.

Second, this Court held that claims "that JUUL mislabels the dosage of nicotine on its pods at 5% when the dosage of nicotine is higher than 5%" were "not preempted." 345 F. Supp. 3d at 1189. That holding was correct: the FDA requires only a "minimum" nicotine warning; any affirmative misstatements are voluntary undertakings by JLI properly subject to generally-applicable duties not to deceive. *See Altria*, 555 U.S. at 82-83 (under FCLAA preemption regime, explaining that a "claim about the deceptive statements 'light' and 'lowered tar and nicotine' … alleges a breach of the duty not to deceive" and were not preempted as relating to the federally-mandated warnings; the "possibility" that "the presence of the federally mandated warnings may bear on the materiality of the … fraudulent statement … does not change [the] case from one about the statements into one about the warnings") (internal quotation marks omitted).

a. The Court should not extend *Colgate*'s nicotine-addiction holding to claims based on omissions of deadly safety defects from the label, and should reaffirm *Colgate*'s holding that "mislabeling" claims are not preempted.

The operative preemptive language—"different from, or in addition to—does not prohibit all state regulation touching on labels subject to federal standards. Rather, the Supreme Court has concluded that similar "different from or in addition to" language allows for state rules that are "equivalent" or "parallel" to federal requirements, in that the standard of conduct does not go beyond that which the federal requirement commands. *Bates*, 544 U.S. at 433 (permitting "equivalent" claims "even if they do not "explicitly incorporate FIFRA's standards as an element

[7] Plaintiffs do preserve for further review their objections to the holding in *Colgate* that the preemptive effect of the TCA, the Deeming Rule, and the Minimum Required Warning Statements applies retroactively. Plaintiffs incorporate by reference the briefing in *Colgate* on this point. Even accepting the Court's retroactivity determination, Plaintiffs note that a claim based on the absence of a nicotine warning *before* the FDA required it would not be preempted because such a claim would be entirely consistent with the FDA regulation. *See Lohr*, 518 U.S. at 495.

of a cause of action"); *Lohr*, 518 U.S. at 494-95 (same for "parallel" medical device claims).

Colgate did not consider the question of whether claims based on a label's failure to disclose risks other than nicotine addiction are preempted. They are not.[8] The "minimum required warning" is just that—minimum—and pertains only to nicotine addiction. The FDA did no study of health and safety, and made no determination whether JLI's products were safe or unsafe, or whether or not any health-and-safety warnings should be required. Instead, the agency kicked the can down the road. *See* April 2020 Guidance at 9 (noting that reports of injuries "affirm[] the importance of the premarket review process ... to scientifically evaluate products based on a public health standard"); Deeming Rule, 81 Fed. Reg. at 28,989-90 (explaining that health risks, including additional exposure warnings, would be evaluated only as part of the premarket review process); *Am. Acad.*, 379 F. Supp. 3d at 492 (FDA did not "address[] public health concerns"). The warning requirement concerns the fact that nicotine is addictive and nothing else.

The FDA itself made clear that state requirements of additional warnings on other topics were not affected by the Minimum Required Warning Statement. The agency expressly found that California's Proposition 65, which requires JLI to include a warning that its products may result in an exposure to certain "chemicals," including nicotine, "known ... to cause cancer, birth defects, or other reproductive harm," *see* Cal. Code of Reg. § 25603(a), on its label, would not be preempted by the warning requirement. *See* Deeming Rule, 81 Fed. Reg. at 28,989 (specifically considering Proposition 65, and concluding that "[n]o State or local laws in effect at the close of the public comment period were identified that FDA determined would be preempted by this final rule."). If California's requirement that JLI disclose health risks is not "different from, or in addition to" the FDA's minimum required warning, then neither are Plaintiffs' claims that the label should have disclosed the risk of serious physical injury. *See Lohr*, 518 U.S. at 496 ("giving

[8] The court in *In re Fontem US, Inc.*, No. 15-01026, 2016 WL 6520142 (C.D. Cal. Nov. 1, 2016), which the Court cited in *Colgate*, did find claims based on a lack of health warnings preempted. *See id.* at *4 ("exposures to toxic chemicals other than nicotine). But the plaintiffs in *Fontem* barely, if at all, argued that the nicotine warning did not encompass health issues, and instead devoted the bulk of their opposition to the more aggressive position that the warning requirements could not preempt *anything* because they were not specific to the products at issue. *See* Opp'n to Mot. to Dismiss, *In re Fontem US Inc.*, No. 15-01026, Doc. 80, at 4-7 (Aug. 5, 2016).

substantial weight to agency's view" of preemption).

It necessarily follows that the Court was correct to hold in *Colgate* that "mislabeling" claims are not preempted. Such claims have nothing to do with the FDA-mandated warning but concern only statements JLI voluntarily placed on the package. *See Altria*, 555 U.S. at 82-83; *Astiana*, 783 F.3d at 758 (finding a mislabeling claim not preempted, and explaining that "while the FDA required the label to include ingredient lists, "FDA regulations do not require [the defendant] to label its products as 'All Natural' or 'Pure Natural'").

JLI's reliance on *Nat'l Meat Ass'n v. Harris* is misplaced, for that case actually shows why health-warning and mislabeling claims are not preempted. 565 U.S. 452 (2012). JLI highlights that the statute at issue in *Harris* (the Federal Meat Inspection Act) included similar "addition to, or different than ... requirements" language. *Id.* at 458. But JLI omits that the Supreme Court identified federal "requirements" that swept broadly in the relevant area, including "extensive regulations to govern the inspection of animals and meat," including "specific provisions for the humane treatment of animals," all enforced by more than "9,000 inspectors, veterinarians, and investigators." *Id.* at 456-57. Given the comprehensive regulations, the Court concluded that any state rule "concern[ing] a slaughterhouse's facilities or operations" would be "additional or different" from the federal rules, and found preempted certain state criminal laws specifically targeting the meat industry. *Id.* at 459-60. The facts here could not be more different. The FDA expressly chose *not* to regulate JLI, and *not* to determine whether health and safety warnings should be required. The only agency "requirement" at issue is the nicotine-addiction warning, making the preemptive sphere correspondingly narrow. And Plaintiffs' claims all arise under statutory or common law of general applicability.

b. Ninth Circuit precedent confirms that labeling and mislabeling claims are not preempted, and that the "misbranding" standard defeats rather than compels preemption.

Cases about cosmetics (which are also subject to FDA regulation) are instructive here. The portion of the FDCA dealing with cosmetics includes preemption language similar to that in the TCA. *See* 21 U.S.C. § 379s(a) (preempting state rules "different from or in addition to, or that is otherwise not identical with" federal cosmetics "requirement[s]"). And the FDA regulates

cosmetics labels, including requiring a specifically-formatted list of ingredients. *See* 21 C.F.R. Part 701. The Ninth Circuit, applying the relevant Supreme Court precedent, has explained that state-law claims about cosmetics labels are not preempted if they are parallel or equivalent to the federal standards. *Astiana*, 783 F.3d at 756-59 (citing *Bates* and *Lohr*). Applying that rule, the Circuit has upheld claims that a cosmetic's label should have "include[d] supplemental statements regarding product accessibility," *Ebner v. Fresh, Inc.*, 838 F.3d 958, 964-96 (9th Cir. 2016), or that a label's use of the term "Natural" was "false or misleading," *Astiana*, 783 F.3d at 756-59; *see also id.* at 758 (explaining that "while the FDA required the label to include ingredient lists, "FDA regulations do not require [the defendant] to label its products as 'All Natural' or 'Pure Natural'"); *Sciortino v. Pepsico, Inc.*, 108 F. Supp. 3d 780, 799 (N.D. Cal. 2015) (under FDCA food labeling preemption, finding Proposition 65 warning not preempted because the state requirements "do not involve the enumerated labeling requirements" imposed by the FDA).

JLI contends that all labeling claims are preempted by virtue of the TCA's misbranding provision, which provides that a tobacco product is "misbranded" if its label is "false or misleading." 21 U.S.C. § 387c(a)(1). But the federal standard is no different than the state-law prohibitions against false or misleading statements. *See Bates*, 544 U.S. at 454 (explaining that "[t]o survive pre-emption, the state-law requirement need not be phrased in the *identical* language as its corresponding FIFRA requirement" and that "jury instructions" can "ensure that nominally equivalent labeling requirements are *genuinely* equivalent"). Again, the cosmetics statute uses the same standard, *see* 21 U.S.C. § 362(a), and the Ninth Circuit has explained consistent state-law claims about cosmetics are not preempted. *See Astiana*, 783 F.3d at 756-59 (explaining that claims challenging "allegedly misleading" statements were consistent with the federal misbranding standard and so not preempted); *Ebner*, 838 F.3d at 964-96 (upholding omission claim because "the state-law duty that Plaintiff seeks to enforce ... is *identical* to Fresh's federal duty in the FDCA: the duty to avoid false or misleading labeling").

4. <u>The TCA expressly preserves advertising claims.</u>

The exception clause of the TCA expressly excepts from preemption state "requirements relating to the ... advertising and promotion of ... tobacco products." 21 U.S.C. § 387p(a)(2)(B).

This provision is susceptible to only one interpretation: "local laws that would otherwise fall within the preemption clause are exempted." *U.S. Smokeless Tobacco Mfg. Co. LLC v. City of New York*, 708 F.3d 428, 433 (2d Cir. 2013); *accord Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence, R.I.*, 731 F.3d 71, 82 (1st Cir. 2013) ("[T]he savings clause[] overrides the standards preemption"). As this Court rightly found in *Colgate*: "The exception clause expressly excepts advertisements from preemption and no aspect of plaintiffs' claims based on allegedly misleading or fraudulent advertising is preempted by the TCA." 345 F. Supp. 3d at 1190. [9]

a. Preemption of rules in connection with "misbranding" does not override the exception clause.

Incredibly, JLI invokes the canon of statutory construction that "the specific governs the general," to argue that advertising claims, which are specifically excepted from preemption, are actually preempted because the more general provisions of the TCA say "[a] tobacco product shall be deemed to be misbranded" if, among many other things, "its advertising is false or misleading." ECF 627 at 7. Having concluded that because misbranding includes among its many aspects false advertising, JLI argues that because the TCA preempts state law "different from, or in addition to," federal "requirements" related to "misbranding," advertising claims are subsumed within that preemption clause regardless of whether advertising claims are specifically excluded from the preemption clause because advertising is too murky a concept for anyone to define. *Id.* This tortured analysis fails for innumerable reasons.[10]

First, JLI's argument flips the general/specific canon on its head. "Misbranding" is a broad concept that bars products from the market for a host of reasons, one of which is false or misleading advertising. Therefore, "advertising" is, if anything, more specific than "misbranding." Similarly, in § 387p itself, the preemption clause (referencing misbranding) is

[9] In a footnote, JLI contends that its "website" is "labeling." ECF 627 at 9 n.5. But as *Colgate* explained, "label is defined as 'display of written, printed, or graphic matter upon the immediate container of an article[.]'" 345 F. Supp. 3d at 1188 (quoting 21 U.S.C. § 321(k)). JLI ignores the unambiguous statutory text, instead citing only one case in which it was undisputed that labeling requirements applied to a website, as well as a 13-year-old FDA guidance letter on food labeling.

[10] As discussed above in section III.B.3.b, Plaintiffs' state-law claims are consistent with the federal misbranding standard and so are not preempted. *See Bates*, 544 U.S. at 453-54; *Astiana*, 783 F.3d at 756-59; *Ebner*, 838 F.3d at 964-66. So even if the misbranding provision could preempt advertising claims, it would not here.

framed as "[i]n general" while the exception clause (specifically exempting advertising) is denoted as the "[e]xception," making the latter more "specific." *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (under the canon "the specific provision is construed as an exception to the general one"). Where it is not obvious which reference is more "specific," the canon is unhelpful. *See Perez-Guzman v. Lynch*, 835 F.3d 1066, 1075-76 (9th Cir. 2016) (declining to apply canon where "each subsection is specific in certain respects and general in others."); *In re Philadelphia Newspapers, LLC*, 599 F.3d 298, 307 (3d Cir. 2010) (canon "only applied where the more specific provision clearly placed a limitation on the general"); Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 187 (2012) (it is "[s]ometimes ... difficult to determine whether a provision is a general or a specific one").

JLI's contorted linguistics would delete the term "advertising" from the preemption exception, which statutory interpretation does not permit. JLI contends "misbranding" is more specific because the terms "advertising and promotion" are left "undefined." ECF 627 at 10. But the implication of an undefined term with broad ordinary meaning is not to assume that it means nothing, but instead that Congress meant the term to sweep broadly. *Cf. Leocal v. Ashcroft*, 543 U.S. 1, 11 (2004) (disregarding complex statutory definition lest the Court "forget that we ultimately are determining the meaning of a term" that has its own "ordinary meaning"). *See Bostick v. Clayton Cty., Ga.*, No. 17-1623, 2020 WL 3146686, at * 2 (U. S. June 15, 2020) ("[W]hen Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule."). And JLI's argument makes no sense because whether a product is "misbranded" depends in part on its "advertising," so any definitional ambiguity carries through.

Finally, JLI's argument has no logical end-point, would swallow the exception clause whole, and defeat the purpose of the statute. *See Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 82 ("[T]his provision was meant to prohibit state regulation narrowly and only with respect to the 'specified and limited areas' listed in the statute.") (quoting H. Rep. 111-58, 2009 U.S.C.C.A.N. 468, 493 (2009)); *U.S. Smokeless Tobacco*, 708 F.3d at 434 ("In light of our presumption that Congress has not limited the exercise of local police powers, we adopt a narrower reading of the preemption clause that also gives effect to the preservation clause."). For example, one way a

tobacco product is "misbranded" is if its manufacturer fails to maintain and produce on request certain "material or information." 21 U.S.C. §§ 387c(a)(10)(A), 387i. On JLI's reasoning, the TCA's exception from preemption of state laws for "information reporting to the State" is also without effect, for any requirement that expanded on the minimum information reporting required to avoid "misbranding" would be preempted. Similarly, if a product is "misbranded" it cannot be sold. 21 U.S.C. § 331(a). On JLI's reasoning, a state's authority to regulate the "sale" and "distribution" of tobacco products would be nullified as well. This would make hash of the carefully-constructed preemption scheme. *See RadLAX*, 566 U.S. at 646-47 (canon "is not an absolute rule" and "can be overcome by textual indications that pointing in the other direction").

b. Amendments to the FCLAA do not support JLI's position.

Next, JLI says that "a broad reading of the [exception] clause's reference to 'advertising and promotion'" (by which JLI means the literal reading) is "undercut" by the TCA's amendment to the Federal Cigarette Labeling and Advertising Act (FCLAA), which has provided for warnings on cigarette packaging and advertising since 1964. ECF 627 at 11. But the FCLAA applies only to cigarettes and only to the specific warnings put in place in 1964 and updated in 1969. It appears in a different title of the U.S. Code from the FDCA, provides a distinct and independent grant of authority to the agency, and has nothing to do with the FDA's regulation of other tobacco products. *See Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167, 174 (2009) ("When conducting statutory interpretation, we must be careful not to apply rules applicable under one statute to a different statute without careful and critical examination."). Indeed, the Deeming Rule itself rejected the false equivalence that JLI makes:

> [W]e note that the preemptive effect depends on the relevant statutes. The preemption provisions of the ... FCLAA ... and the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA) (15 U.S.C. 4406), which apply to cigarettes and smokeless products, respectively, are significantly different from section 916 of the FD&C Act. For example, the FCLAA and CSTHEA provisions expressly preempt State and local regulation of the content of cigarette and smokeless product advertisements, while section 916(a)(2)(B) of the FD&C Act exempts State and local advertising restrictions from preemption.

81 Fed. Reg. at 28,989. *Cf. Lohr*, 518 U.S. at 496 ("giving substantial weight to agency's view" of preemption). And JLI's argument is an abrupt about-face from the view it advanced in *Colgate*: "[S]ection 203 of the TCA amended the preemption provision of the FCLAA; it has nothing to do with the preemption provision that the TCA created in the [FDCA]."[11] The comparison falls even further apart given that the amendment to the FCLAA refers only to tobacco-specific state positive enactments ("statutes and ... regulations, based on smoking and health), not the generally-applicable state-law duties at issue in all of the complaints in this case.[12]

Nor does the specific amendment the TCA made to the FCLAA have the implications JLI would give it. Since 1969, the FCLAA had provided that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes." *Altria Grp.*, 555 U.S. at 78-79 (quoting 15 U.S.C. § 1334(b)). This provision preempted state restrictions on advertising and promotion related to "smoking and health," but left unaffected claims based on generally-applicable duties "not to deceive." *Id.* at 82. In *Lorillard Tobacco Co. v. Reilly*, however, the Supreme Court held that the FCLAA preempted state regulations restricting the "location" of cigarette advertising, even if they did not affect the "content." 533 U.S. 525, 548-49 (2001). The amendment to the FCLAA permitting state "restrictions on the time, place, or manner ... of the advertising or promotion of any cigarettes" was intended to reverse that portion of *Lorillard*, nothing more. *See Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 80 ("[T]his provision was design to 'essentially reverse' the *Lorillard* preemption ruling.") (quoting Banthin & Daynard, *supra*, at 69).

If anything, the amendment to the FCLAA (inapplicable to e-cigarettes) undermines JLI's position. After interpreting the TCA to gut the exception clause, JLI assures the Court that states

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[11] Def's Reply in Support of Mot. to Dismiss, *Colgate v. JUUL Labs., Inc.*, No. 18-2499, Doc. 57, at 4 (Sept. 12, 2018). JLI made this argument in its successful motion to preempt nicotine-addiction labeling claims in *Colgate*, and principles of judicial estoppel apply.

[12] The two preemption provisions also have distinct purposes. The "overall purpose of the [FCLAA's] preemption provision ... is to ensure that federal regulation in this respect is 'not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulation." *Nat'l Ass'n of Tobacco Outlets*, 731 F.3d at 80-81 (quoting 15 U.S.C. § 1331). One need not squint to see the purpose of the FDCA preemption provision; it's right there in the title: "Preservation of State and local authority." 21 U.S.C. § 387p.

still retain the authority to institute "time, place, and manner restrictions." ECF 627 at 4. But the exception clause exempts "advertising" from preemption, not "time, place, and manner restrictions," and the amendment to the FCLAA confirms that Congress knew how to write "time, place, and manner" when it intended to do so. *See, e.g.*, *Jama v. ICE*, 543 U.S. 335, 341 (2005) ("We do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown elsewhere in the same statute that it knows how to make such a requirement manifest.").[13] If Congress meant to say "time, place, and manner" in the exception clause, it would have done so.

5. JLI's modified-risk argument is absurd on its face.

Everyone—JLI, Plaintiffs, and the FDA—agrees that JLI's products are not "modified risk tobacco products." ECF 627 at 12. If JLI's products were "modified risk tobacco products," then they could not be sold unless and until each of the following occurred: (1) an "application for a modified risk product" is filed including "research findings ... relating to the effect of the product on tobacco-related diseases and health-related conditions;" (2) the application is made "publicly available" for "comments;" (3) the application is "referred to the Tobacco Products Scientific Advisory Committee" for "recommendations;" and (4) specific findings are made related to harm reduction and health promotion. 21 U.S.C. § 387k(a), (d)-(i). None of those things has happened and there is no evidence any will happen: JLI's position is that its "products are not 'modified risk tobacco products'" full stop. ECF 627 at 12.

Yet with a straight face JLI maintains that mislabeling and advertising claims against it are preempted as by federal "requirement[s] ... related to ... modified risk tobacco products." 21 U.S.C. § 387p(a)(2)(A). In other words, JLI's position is that it may evade federal regulation by disclaiming its products are "modified risk tobacco products" while simultaneously enjoy immunity against core state police powers by invoking the preemptive effect of non-existent

[13] This argument may ring familiar to the Court; it too was in JLI's *Colgate* briefing: "If anything, the different language that the TCA added to the FCLAA and the [FDCA] only underscores JUUL Labs' point, because 'when Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion[.]'" *Colgate* Reply at 4 (quoting *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002)).

regulation. But the absence of regulation is not regulation, s*ee Freightliner*, 514 U.S. at 286; *Sprietsma*, 537 U.S. at 65, and it is implausible (and would be unprecedented) that Congress intended to create a regulation-free zone applicable only to tobacco companies.

C. Plaintiffs' claims are not impliedly preempted.

According to JLI, everyone—the parties in this case, the Court in *Colgate*, numerous other courts including the First and Second Circuits, the FDA, and Congress itself—has simply wasted their time worrying about the express preemption provision in 21 U.S.C. § 387p. Because, as it turns out, all that ink was beside the point: "all of Plaintiffs' state-law claims are ... preempted" under sweeping theories of obstacle preemption with a touch of impossibility thrown in. ECF 627 at 13. JLI's argument—that literally every state-law claim in three diverse complaints filed by very different groups of plaintiffs is prohibited—is a poorly-masked invocation of *field* preemption, which "reflects a congressional decision to foreclose *any* state regulation in the area" touched on by federal law. *Arizona v. United States*, 567 U.S. 387, 401 (2012) (emphasis supplied). That clearly is not what the TCA does; instead Congress adopted the goal of "Preservation of State and local authority," subject only to the "Preemption of certain State and local requirements," a preemption clause itself qualified by the exception clause and the rule of construction. 21 U.S.C. § 387p. Liberation of tobacco and e-cigarette companies from all state-law restrictions would be remarkable, but has no basis in the statute written by Congress.

1. JLI's boundless obstacles-and-purposes preemption analysis is foreclosed by the express preemption clause.

The express preemption clause, paired with the exception clause and rule of construction, is comprehensive. It answers every question presented by JLI's motion and gives no license for freewheeling inquiry into loosely-defined "purposes" and "obstacles." Through the statutory text, Congress determined which state laws would be preempted and which would survive. JLI says that Congress' "objective" was for the FDA to conduct a "holistic analysis" for tobacco products. ECF 627 at 14. That's true as far as it goes, but it only goes so far. The Supreme Court has often recognized that "no legislation pursues its purposes at all costs." *CTS Corp. v. Waldburger*, 573 U.S. 1, 12 (2014) (citation omitted). The plain text of the TCA shows that Congress accepted, for

example, state advertising regulation and product liability claims, despite whatever limitations those might have on the law's pursuit of a particular purpose. *See Rodriguez v. United States*, 480 U.S. 522, 526 (1987) ("Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law."). And there are "competing values" here in spades, most obviously the provision of traditional remedies for the millions injured by tobacco. The implication that "Congress would have barred most, if not all, relief" for persons so injured, while "granting complete immunity ... to an entire industry that, in the judgment of Congress, needed *more* stringent regulation," is "perverse." *Lohr*, 518 U.S. at 487 (emphasis supplied).

JLI argues that an express preemption provision "does not foreclose the application of ordinary implied preemption principles." ECF 627 at 17. This is a straw man argument. Yes, courts have rejected the argument that an express preemption clause, by failing to say anything one way or another about a particular claim, through its mere presence *categorically* excludes any implied preemption of that claim. *See, e.g.*, *Freightliner*, 514 U.S. at 288-89; *Atay*, 842 F.3d at 704 (presence of "express preemption clause creates a 'reasonable inference'" of no implied preemption) (citation omitted). But no court—certainly none that JLI cites—has entertained a claim of implied preemption that *contradicted* the terms of an express preemption provision. *See Bostick*, 2020 WL 3146686, at * 18 ("Judges are not free to overlook plain statutory commands on the strength of nothing more than suppositions about intentions or guesswork about expectations."). Instead, courts have analyzed implied preemption as a means to fill *gaps* in the statute and answer questions left unanswered by express preemptive language. *See Lamie v. U.S. Tr.*, 540 U.S. 526, 538 (2004) ("There is a basic difference between filling a gap left by Congress' silence and rewriting rules that Congress has affirmatively and specifically enacted.").

Take *Geier*, where an injured motorist brought common law design defect claims based on the car's failure to have an airbag. 529 U.S. at 865. The question was whether the claim was preempted by a NHTSA regulation that "gave car manufacturers a choice as to whether to install airbags." *Id.* The express preemption clause precluded states from establishing "any safety

standard ... which is not identical to the Federal standard." *Id.* at 867. The Supreme Court interpreted this language to refer only to positive enactments—"state statutes and regulations"—and not "common-law tort actions." *Id.* at 867-68. And, as discussed above in section III.B.1, the Court interpreted the "saving clause" merely to provide a "special kind of defense." *Id.* at 869. So the express preemption clause had nothing to say one way or another about common law claims, leading the Court to conduct an implied preemption analysis.[14]

Buckman Co. v. Plaintiffs' Legal Comm., is even further afield. 531 U.S. 341 (2001). In that case, the plaintiffs asserted a state-law fraud claim based solely on purported misrepresentations made to the FDA during the premarket approval process. *Id.* at 343. This "fraud-on-the-FDA" claim was not grounded in tort at all, but instead "exist[ed] solely by virtue of the FDCA disclosure requirements." *Id.* at 352-53; *see also id.* at 353 (explaining that "the existence of these federal enactments is a critical element in their case"). *Buckman* thus stands only for the unremarkable proposition that a private litigant may not hijack a federal process to create a claim for relief, even if an express preemption clause does not explicitly say so. This is just common sense: it would be odd for Congress to expressly preclude plaintiffs from stepping into the shoes of a federal agency; doing so is prohibited by the very act of establishing an agency. Just as Congress, when it defines a federal crime, does not generally say "and no state may act as the U.S. Attorney," but everyone knows that to be true. *Cf. Arizona*, 567 U.S. at 402 (comparing the plaintiff's clam in *Buckman* with "[p]ermitting the State to impose its own penalties for [] federal offenses"). For this reason, courts regularly take *Buckman* as *sui generis*, applicable only to claims based solely on "fraud-on-the-FDA," which Plaintiffs have not pleaded here, and inapplicable to claims premised on "state-law dut[ies]," which Plaintiffs have. *See, e.g.*, *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1229-33 (9th Cir. 2013) (en banc); *id.* at 1235

[14] *Nat'l Fed. of the Blind*, is the same. There, the case concerned airport kiosks, but the preemption clause referred only to airlines' "prices, routes, or services," and. 813 F.3d at 726. Once the court concluded that kiosks were not "services," the express preemption clause did not answer one way or the other whether the plaintiffs' claims were preempted by "exhaustive" federal regulation of "accessibility of airport kiosks." *Id.* at 733. Also off-point is *Atay*, 842 F.3d at 704, which merely "assum[ed]" an implied preemption analysis was appropriate because it found no preemption regardless, and *Backus v. Gen. Mills, Inc.* No. 15-1964, 2018 WL 6460441, at*6 (N.D. Cal. Dec. 10, 2018), which did not involve any express preemption clause at all.

(Watford, J., concurring) ("*Buckman* left intact claims 'relying on traditional state tort law which had predated the federal enactments' in question") (quoting *Buckman*, 531 U.S. at 353).

Ironically, the correct rule is stated in a tobacco case under the FCLAA: "When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of the legislation." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 517 (1992) (plurality opn.) (internal quotation marks omitted); *Volkswagen*, 959 F.3d at 1211 ("If the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.") (citation omitted). Here, the breadth and depth of the express preemption statute provides that "reliable indicium" and ends the inquiry. JLI's contention otherwise fundamentally misunderstands the work of statutory interpretation. JLI asks the Court to look to "purpose and intended effects," ECF 627 at 14, but purposive inferences can never displace plain text. The Supreme Court has "stated time and again that courts must presume that a legislature says in a statute what it means and means in a statute what it says. When the words of a statute are unambiguous, then, this first canon is also the last: judicial inquiry is complete." *Barnhart*, 534 U.S. at 461-62 (citations omitted). JLI "should not seek to amend the statute by appeal to the judicial branch." *Id.* at 462.

2. The FDA's deferred enforcement policy does not expand the preemptive scope of the TCA.

JLI contends that Plaintiffs' claims "frustrate a federal method," referring to premarket review. ECF 627 at 15. Of course the FDA has not conducted premarket review, so JLI's argument is that state-law claims present an obstacle to FDA's "defer[ed] enforcement of the premarket authorization requirement." *Id.* at 15. Even assuming the federal "method" was relevant given the express preemption terms, preemption does not follow from the FDA's *failure* to apply the method. Obstacle preemption, even where it is possible, "must turn on whether state law conflicts with the text of the relevant federal statute or with the regulations authorized by that

text." *Wyeth v. Levine*, 555 U.S. 555, 588 (2009). There "is no federal preemption *in vacuo*, without a constitutional text, federal statute, or treaty made under the authority of the United States." *Kansas v. Garcia*, 140 S. Ct. 791, 801 (2020) (internal quotation marks omitted). If follows, *a fortiori*, that the only "method" relevant to preemption is one envisioned by Congress, not one invented by an agency, no matter how creative. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019). ("[T]he only agency actions that can determine the answer to the pre-emption question, of course, are the agency actions taken pursuant to the FDA's congressionally delegated authority."). The FDA may have thought it prudent to "allow[] unapproved tobacco products to be manufactured, advertised, and sold," but this "across-the-board suspension of the [TCA]'s premarket approval process" is "inconsistent with the statute." *Am. Acad.*, 379 F. Supp. 3d at 492. Outside "the scope of its congressionally delegated authority, [] an agency literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State." *Merck*, 139 S. Ct. at 1679.[15]

3. JLI lacks any colorable impossibility argument.

Courts sometimes find preemption where it is "impossible for a private party to comply with both state and federal requirements," *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 480 (2013) (citation omitted). Of course, none of the Supreme Court's impossibility preemption cases contemplate a claim of preemption in contradiction to an express preemption provision. *See id.* at 492-93 (suggesting that "we are left to divine Congress' will from the duties the statute imposes" only because "the FDCA's treatment of prescription drugs includes neither an express pre-emption clause ... nor an express non-preemption clause"). So, for example, any claim that product liability claims are preempted under impossibility principles must be rejected as running headlong into the rule of construction.

[15] JLI's citations are off-point. *McDaniel v. Wells Fargo Invs., LLC*, did not involve an express preemption clause. 717 F.3d 668, 674 (9th Cir. 2013). Both *Arizona*, 567 U.S. at 387, and *Int'l Paper Co. v. Oullette*, 479 U.S. 481, 484 (1987), involved field preemption, which is inapplicable here. *Chae v. SLM Corp.*, involved actual regulatory requirements, not the absence of them, and did not consider an argument that a particular "method" justified ignoring the plain statutory text. 593 F.3d 936, 950 (9th Cir. 2010). And *Allergan USA, Inc. v. Imprimis Pharms., Inc.*, No. 17-1551, 2019 WL 4545960, at *10 (C.D. Cal. Mar. 27, 2019), is about whether a federal standard was violated and so triggered state-law duties, not preemption.

But even putting that aside, "impossibility pre-emption is a demanding defense," *Wyeth*, 555 U.S. at 573, one that JLI cannot make out here. In *Bartlett*, on which JLI relies, the plaintiff brought a design-defect claim against a generic drug manufacturer, a claim that the Supreme Court determined "would require redesigning the drug" or changing the label. 570 U.S. at 483-87. Generic drugs receive FDA authorization because they are simply copies of the brand-name drug: "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based." *Id.* at 483-84; *see also PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (explaining that "generic drug manufacturers have an ongoing federal duty of 'sameness'"). Therefore, because "redesign was not possible" and "federal law prevents generic drug manufacturers from changing their labels," it was "impossible for" generic "manufacturers to comply with both state and federal law" and the state-law claims were preempted. *Bartlett*, 570 U.S. at 483-88.

Conversely, in *Wyeth*, the Supreme Court considered a failure-to-warn claim against a brand-name manufacturer. 555 U.S. at 564. The Court held the lawsuit was not preempted because it was possible for the brand-name manufacturer, unlike a generic manufacturer, to independently change its label and seek FDA approval only after the fact. *Id.* at 569, 572-73; *see also Mensing*, 564 U.S. at 613 ("A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label."). It made no difference that any label changes were ultimately subject to FDA approval: "absent clear evidence that the FDA would not have approved a change to [the drug's] label, we will not conclude it was impossible for Wyeth to comply with both federal and state requirements," and "Wyeth has offered no such evidence." *Wyeth*, 555 U.S. at 571- 572. Critically, the Court demanded actual evidence of impossibility (both *Wyeth* and *Bartlett* came to the Court on a full record after trial), later clarifying that "showing that federal law prohibited the manufacturer from adding a warning ... requires the drug manufacturer to show that it fully informed the FDA of the justifications for the warning ... and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include the warning." *Merck*, 139 S. Ct. at 1678.

As Judge Tigar has explained in a thorough opinion, *Wyeth* and *Bartlett* yield a simple test

for impossibility preemption: "First, courts must determine whether [a] manufacturer may independently take action that complies with both state and federal law. An action is independent under this analysis if the manufacturer can take such action without prior FDA approval, even if the FDA may subsequently reject approval of the action post hoc. If independent action is not possible, then the state-law claims are preempted. If independent action is possible, then the claims are preempted only if there is clear evidence that the FDA would not grant approval." *Holley v. Gilead Sci., Inc.*, 379 F. Supp. 3d 809, 821-25 (N.D. Cal. 2019) (collecting cases).

JLI fails that test. JLI contends that "[t]o the extent that liability on state-law claims would cause JLI to modify JUUL products, those state-law claims are" preempted because JLI would need FDA approval to modify its design. ECF 627 at 16. But the FDA has never approved JLI's product designs; any relevant claims target a design created by JLI alone. Per Judge Tigar: "that a [] manufacturer cannot market a redesigned version of an approved [product] without first seeking FDA approval does not address whether the manufacturer was required to use the allegedly defective design in the first place." *Id.* at 824 (citation omitted). JLI "has cited no federal law that restricts a [tobacco product] manufacturer from designing a reasonably safe product *prior* to FDA approval." *Id.* (citation omitted). The design being the result of JLI's "independent action," the focus then shifts to whether there is "clear evidence" the FDA would not approve a modified design. *Id.* at 821. This showing is "difficult" in the general case, *Merck*, 139 S. Ct. at 1678, but particularly so here where the FDA (1) has never actually weighed in on a JLI product design and (2) has deferred enforcement of premarket review requirements while JLI markets and sells products with unapproved designs. *Cf. Wyeth*, 555 U.S. at 570 ("And the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept—neither Wyeth nor the United States has identified a case in which the FDA has done so."). The Court need not dwell on this issue: the defense requires "clear evidence" and JLI has not produced any evidence at all.

IV. CONCLUSION

JLI's motion should be denied.

Dated: June 29, 2020

Respectfully submitted,

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APPENDIX

21 U.S.C. § 387p

Preservation of State and local authority

(a) In general

(1) Preservation

Except as provided in paragraph (2)(A), nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products. No provision of this subchapter shall limit or otherwise affect any State, tribal, or local taxation of tobacco products.

(2) Preemption of certain State and local requirements

(A) In general

No State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

(B) Exception

Subparagraph (A) does not apply to requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products. Information disclosed to a State under subparagraph (A) that is exempt from disclosure under section 552(b)(4) of Title 5 shall be treated as a trade secret and confidential information by the State.

(b) Rule of construction regarding product liability

No provision of this subchapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

CERTIFICATE OF SERVICE

I hereby certify that on June 29, 2020, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will automatically send notification of the filing to all counsel of record.

By: /s/ *Sarah R. London*
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